Remarks

The Office Action mailed August 1, 2006 has been received and reviewed. Claims 1, 10, 20, 32, 56, and 63 having been amended and claims 75-78 having been added, the pending claims are claims 1-78. Reconsideration and withdrawal of the rejections are respectfully requested.

Each independent claim has been amended to refer to the polymers as miscible to clarify that the phrase "miscible polymer blend" refers to the miscibility of the polymers relative to each other. Each independent claim has also been amended to recite that the miscible polymer blend "controls delivery of the active agent." Each independent claim has also been amended to recite specific lists of polymers in the miscible polymer blends. New claims 75-78 are directed to a method for tuning the delivery of an active agent to a subject, and a method of forming a tunable active agent delivery system. Each of these amended and new claims is supported by the application as originally filed, including the text added to the specification referenced below.

The specification at pages 30-32 has been amended to incorporate language from the referenced patent applications, which were incorporated by reference at page 62 of the present application. For example, the text added at page 30, line 25 of the present application is from the three applications referenced in the previous paragraph. The text added at page 31, line 13 of the present application is from the application referenced in the previous paragraph. The text added at page 32, line 23 of the present application is from the application referenced in the previous paragraph. The correction to the specification at page 31, line 7 would be clear to one of skill in the art upon reading the specification, in particular that at pages 29-32.

Interview Summary

An Interview was conducted on October 18, 2006, between Examiner James W. Rogers, Examiner Mike Hartley, and Applicants' Representatives Ann M. Mueting and David P. Ruschke. Inventors Randall V. Sparer, Christopher M. Hobot, and SuPing Lyu took part in the interview telephonically. Applicants thank the Examiners for the courtesy extended during this

interview. The statements provided by the Examiner in the interview summary dated October 18, 2006 form a complete and accurate record of this interview. A copy of the slides discussed is submitted herewith as Exhibit A.

Applicants appreciate the Examiners' suggestion that specific first and second polymers be incorporated into claim 1 (and each independent claim). Accordingly, such amendments are presented herein. It is respectfully submitted that the claims as currently presented recite sufficient descriptive parameters that describe unique and nonobvious combinations of miscible polymers in a miscible polymer blend that controls delivery of the active agent.

The 35 U.S.C. §102 Rejections

The Examiner rejected claims 1-74 under 35 U.S.C. §102(b) as being anticipated by Hossainy et al. (U.S. Patent No. 6,153,252). The Examiner rejected claims 1-74 under 35 U.S.C. §102(b) as being anticipated by Whitbourne et al. (U.S. Patent No. 6,110,483). These rejections are respectfully traversed and rendered moot by the amendments presented herein.

The 35 U.S.C. §103 Rejections

The Examiner rejected claims 1-74 under 35 U.S.C. §103(a) as being unpatentable over Hossainy et al. (U.S. Patent No. 6,153,252). The Examiner rejected claims 1-74 under 35 U.S.C. §103(a) as being unpatentable over Whitbourne et al. (U.S. Patent No. 6,110,483). These rejections are respectfully traversed and rendered moot by the amendments presented herein.

In response to the Examiner's comments in the Office Action, Applicants incorporate herein by reference the arguments presented in the previous Response dated June 28, 2006 and emphasize that there is no teaching or suggestion in either Hossainy et al. or

Whitbourne et al. of Applicants' invention. In particular, there is no teaching or suggestion of which of the many polymers listed to select to provide Applicants' invention.

Furthermore, Applicants' claims distinguish the cited art at least because there is no teaching or suggestion in either Hossainy et al. or Whitbourne et al. of the criteria being used by Applicants to select the desired combinations of miscible polymers to create a miscible polymer blend. That is, in addition to the lists of specific miscible polymers, the claims recite sufficient descriptive parameters for unique and nonobvious combinations of miscible polymers in a miscible polymer blend that controls delivery of the active agent.

For example, with respect to the composition claims, there is no teaching or suggestion of the combination of components that form an active agent delivery system having a target diffusivity, the system comprising an active agent and a miscible polymer blend that controls delivery of the active agent; wherein: the active agent is hydrophobic and has a molecular weight of no greater than about 1200 g/mol; and the miscible polymer blend comprises at least two miscible polymers, each with at least one solubility parameter, wherein: the difference between the solubility parameter of the active agent and at least one solubility parameter of at least one of the polymers is no greater than about 10 $J^{1/2}/cm^{3/2}$, and the difference between at least one solubility parameter of each of at least two polymers is no greater than about 5 $J^{1/2}/cm^{3/2}$; at least one polymer has an active agent diffusivity higher than the target diffusivity and at least one polymer has an active agent diffusivity lower than the target diffusivity; the molar average solubility parameter of the blend is no greater than 25 $J^{1/2}/cm^{3/2}$; and the swellability of the blend is no greater than 10% by volume (claim 1).

It is respectfully submitted that Hossainy et al. and Whitbourne et al., disclose classes of polymers, however, not every member of every class of such polymers is miscible. Thus, for the composition claims, Applicants have provided a manner of selection of the polymers for use in an active agent delivery system having a target diffusivity, for example, based on the following parameters:

the difference between the solubility parameter of the active agent and at least one solubility parameter of at least one of the polymers;

the difference between solubility parameter of each of at least two polymers;

at least one polymer has an active agent diffusivity higher than the target diffusivity;

at least one polymer has an active agent diffusivity lower than the target diffusivity;

the molar average solubility parameter of the blend; and

the swellability of the blend.

With respect to the method claims, for example, there is no teaching or suggestion of selecting the polymers for use in a method of designing an active agent delivery system for delivering an active agent over a preselected dissolution time (t) through a preselected critical dimension (x) of a miscible polymer blend that controls delivery of the active agent, the method comprising: providing an active agent having a molecular weight no greater than about 1200 g/mol; selecting at least two miscible polymers, wherein: the difference between the solubility parameter of the active agent and at least one solubility parameter of each of the polymers is no greater than about 10 $J^{1/2}/cm^{3/2}$, and the difference between at least one solubility parameter of each of the at least two polymers is no greater than about 5 $J^{1/2}/cm^{3/2}$; the difference between at least one Tg of each of the at least two polymers is sufficient to include the target diffusivity; combining the at least two polymers to form a miscible polymer blend; and combining the miscible polymer blend with the active agent to form an active agent delivery system having the preselected dissolution time through a preselected critical dimension of the miscible polymer blend (claim 56).

It is respectfully submitted that Hossainy et al. and Whitbourne et al., disclose classes of polymers, however, not every member of every class of such polymers is miscible. Thus, for the method claims, Applicants have provided a manner of selection of the polymers for

use in a method of designing an active agent delivery system for delivering an active agent, for example, based on the following parameters:

the difference between the solubility parameter of the active agent and at least one solubility parameter of each of the polymers;

the difference between at least one solubility parameter of each of the at least two polymers;

the difference between at least one Tg of each of the at least two polymers is sufficient to include the target diffusivity;

a preselected dissolution time; and

a preselected critical dimension of the miscible polymer blend.

Thus, not only have Applicants amended the claims to recite specific lists of polymers, Applicants' claims provide a manner of selection of the polymers based on the various recited parameters discussed above. Withdrawal of each of the rejections is respectfully requested.

Summary

It is respectfully submitted that the pending claims 1-78 are in condition for allowance and notification to that effect is respectfully requested. The Examiner is invited to contact Applicants' Representatives, at the below-listed telephone number, if it is believed that prosecution of this application may be assisted thereby.

Respectfully submitted
By
Mueting, Raasch & Gebhardt, P.A.
P.O. Box 581415
Minneapolis, MN 55458-1415
Phone: (612) 305-1220
Facsimile: (612) 305-1228
Customer Number 26813

November 1, 2006
Date

By: Ann M Mueting
Ann M. Mueting
Reg. No. 33,977
Direct Dial (612) 305-1217

CERTIFICATE UNDER 37 CFR §1.10:
"Express Mail" mailing label number: EV 201877625 US Date of Deposit: November 1, 2006
The undersigned hereby certifies that this paper is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR §1.10 on the date indicated above and is addressed to Mail Stop RCE, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

By: Deb Schurmann
Name: Deb Schurmann